Open for outbreaks

In the onslaught of the COVID-19 pandemic, the open sharing of materials, information and data is gaining increasing importance in biotech.

The coronavirus pandemic is posing profound challenges to our healthcare infrastructure, economic systems and social fabric. Many governments have been caught flat-footed, scrambling to 'flatten the curve' of community spread through social distancing or sheltering in place, as they attempt to maintain increasingly overwhelmed hospital services and mitigate shortages in medical supplies. The biotech industry is doing its part by fast-tracking the production of diagnostics, rapidly repurposing existing treatments, and accelerating the discovery and development of new experimental therapeutics and vaccines that specifically target the virus. But with traditional product development times taking anywhere from several years to over a decade, researchers are seeking out new ways of collaborating, forging new types of partnerships, and embracing new clinical development paths. The post-COVID-19 world requires not only a joined-up global healthcare research ecosystem capable of open publication and rapid sharing of data and clinical materials, but also more open, flexible and adaptable development models that can speed innovative products to the bedside.

As *Nature Biotechnology* went to press, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) had caused almost 34,830 deaths worldwide, with over 735,560 confirmed cases since its emergence in December. Open data on the epidemiology of the spread of COVID-19 made available via the World Health Organization (WHO) and Johns Hopkins University has been key in tracing the pandemic's spread across the globe.

The biopharmaceutical industry has rapidly mobilized to address the global healthcare emergency, applying artificial intelligence to accelerate the discovery of small-molecule, peptide and monoclonal antibody leads, pushing forward experimental modalities like nucleic acid–encoded antibodies or DNA/RNA vaccines, and improvising in preclinical and clinical development to accelerate products through the pipeline in record times.

None of these discovery efforts would have been possible without the rapid sharing of the SARS-CoV-2 genome sequence on 10 January, with subsequent depositions from different patients isolates lodged in various public repositories (e.g., NCBI, GISAID and ViPR). This has enabled analysis of the pandemic's history and revealed the close relation of SARS-CoV-2 to bat coronaviruses. Similarly, the availability of atomic structures of the virus spike (S) protein in the Protein Data Bank has enabled open efforts in protein engineering (for example, the Institute for Protein Design's use of citizen science in its FoldIt game) and computer-assisted design of small molecules (for example, Innophore's open modeling efforts).

In the biotech sector, it has been anything but business as usual. As supply-chain disruptions have created reagent shortages, creative ways have been found to share materials: for example, laboratories in the San Francisco area donated RNA extraction kits to a COVID-19 diagnostic lab following an announcement from Qiagen that it was struggling to meet orders for the reagents. Groups specializing in 3D printing and additive manufacturing have provided parts to repair ventilators or provided specs for turning snorkels into CPAP face masks. The Biotechnology Innovation Organization trade association has set up a hub to connect companies with resources to other companies that need them. Ginkgo Bioworks has set aside $25 million for 'foundry work' to support R&D efforts, and various SARS-CoV-2 components are being made available in community resources like Addgene, with constructs encoding key enzymes for diagnostics available via Open Enzymes.

Business transactions have also accelerated. Startups and discovery shops are rapidly partnering with larger companies that have bulk manufacturing and clinical development expertise. The name of the game has been collaboration and accelerated transactions rather than maximizing intellectual property (IP) value and protecting proprietary data — an aspect where open material transfer agreements and proposed WHO IP pools can also reduce red tape. In clinical development, master protocols and adaptive clinical trials are being designed to speed drug testing, and datasets are being made available by the COVID-19 Open Research Dataset Challenge and the Observational Health Data Sciences and Informatics consortium.

Although these systems and practices enabling open sharing have proven key in the public health response to COVID-19, blind spots remain.

In all but a few countries, like Korea, Singapore and Taiwan, the failure to make diagnostic tests for COVID-19 rapidly available has hampered tracking of infections. In the United States, the Centers for Disease Control and Prevention's botched test (which showed sporadic reactivity in the negative control of one of the three assay components), overly strict FDA rules and the sidelining of private labs were serious missteps.

In terms of public health surveillance, the use of artificial intelligence to track GPS data on infected individuals in countries like Korea and China is raising questions about the balance between public health safety and individual privacy rights — and whether the latter should be temporarily relaxed in a public health emergency.

Efforts have also been hampered by the lack of a mechanism for open sharing of clinical samples from COVID-19 patients. Patient sera are a starting point for monoclonal antibody discovery efforts and immune-cell profiling efforts. Transfer of research materials across national borders is a lengthy process in the best of times. Clearly, the global health community's continued insistence on national sovereignty over biological resources during epidemics is wrongheaded. COVID-19 demonstrates the need for a WHO central repository or clearinghouse to make clinical samples accessible to all. The Foundation for Innovative New Diagnostics' specimen bank is an example of how such a repository could be set up.

Since its inception, the biotech enterprise has been dominated by proprietary processes and asymmetric information sharing. COVID-19 is a moment when it can shift its center of gravity from the traditional 'need to know' model to a 'need to share' model. The question is: do we continue with the old ways of working or do we find new ways that will unleash a new wave of biotech innovations? Normally there would be little chance of this happening. But now is not a normal moment. ❐

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